K061876

SECTION 6. - 510(k) Summary
(As Required By 21 CFR 807.92(a))

OCT 16 2006

A. Company Information

Codman & Shurtleff, Inc.
325 Paramount Drive
Raynham, MA 02767-0350
Establishment Registration Number: 1226348

B. Contact Person

Susan Kagan
Senior Regulatory Affairs Specialist
Telephone Number: 508-880-8097
Fax Number: 508-828-2777

DATE: June 30, 2006

C. Device Information

Propriety / Trade Name: CODMAN® VPV™ System
Common Name: Hydrocephalus Shunt System
Predicate Device: CODMAN® VPV™ System (K050739)

D. Classification

This device has been placed in Class II for Central Nervous System Fluid Shunt and Components devices per 21 CFR 882.5550 (84JXG).
Classification Panel: Neurology

E. Device Description

The CODMAN® VPV™ System (VPV) is an accessory (multiple use) indicated for use only with the CODMAN® HAKIM Programmable Valve, in the treatment of hydrocephalus when shunting cerebrospinal fluid (CSF) from the ventricles of the brain. The system is comprised of the program unit, transmitter unit, a power cord, carrying case, and ultrasound gel. The VPV System allows the clinician to noninvasively increase or decrease the valve setting to meet the patient's particular clinical needs.

F. Indications For Use

The CODMAN® VPV™ system is designed for use only with CODMAN® HAKIM™ Programmable Valves in the treatment of hydrocephalus when shunting cerebrospinal fluid (CSF) from the ventricles of the brain. It is used to non-invasively adjust the CODMAN HAKIM Programmable Valve to the selected setting and provides confirmation of the valve adjustment, **without the need for radiographic imaging when an "Adjustment Complete" message is displayed.**

G. Device Testing

Substantial equivalence for this device was based upon performance testing (physical and mechanical testing) and *in vitro* testing. Test results demonstrate substantial equivalence of the product to commercially distributed predicate devices for the same intended use.

H. Statement of Substantial Equivalence

The CODMAN VPV System is identical to the currently marketed predicate VPV device (K050739) in terms of physical characteristics, programming and procedure. The CODMAN VPV System is substantially equivalent to Medtronic's PS Medical Strata® Valves and Handtools (K040943) with regard to Indications for Use and labeling.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 16 2006

Codman & Shurtleff, Inc.
% Ms. Susan Kagan
Senior Regulatory Affairs Specialist
325 Paramount Drive
Raynham, Massachusetts 02767-0350

Re: K061876
Trade/Device Name: CODMAN® VPV™ System
Regulation Number: 21 CFR 882.5550
Regulation Name: Central nervous system fluid shunt and components
Regulatory Class: II
Product Code: JXG
Dated: September 6, 2006
Received: September 7, 2006

Dear Ms. Kagan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for P. Mkr

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 5. Indication for Use Statement

Indications for Use

510(k) Number (if known): K061876

Device Name: CODMAN® VPV™ System

Indications For Use:

The CODMAN® VPV™ System is designed for use only with CODMAN® HAKIM™ Programmable Valves in the treatment of hydrocephalus when shunting cerebrospinal fluid (CSF) from the ventricles of the brain. It is used to non-invasively adjust the CODMAN HAKIM Programmable Valve to the selected setting and provides confirmation of the valve adjustment, **without the need for radiographic imaging when an "Adjustment Complete" message is displayed.**

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K061876